



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

2382-186

Date of Issuance:

10/26/17

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 10/26/19

Name of Pesticide Product:

Effipro Topical Solution for Cats

Name and Address of Registrant (include ZIP Code):

Michelle Foster
 Associate Manager, Regulatory Affairs
 Research & Development/Virbac Corporation
 3200 Meacham Boulevard
 Fort Worth, TX 76137

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03
 Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

10/26/17

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product and is extending the two-year registration restriction. This registration is time-limited and expires 10/26/19.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the initial registration notice dated January 14, 2011.
4. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 09/10/2015
- Alternate CSF 1 dated 08/04/16

Page 3 of 3
EPA Reg. No. 2382-186
Decision No. 531238, 531237

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

Master Label

[Optional Text Appears In Brackets. The final label may include some or all of the optional text on the front, back, side panels, or insert.]

Front Panel and Insert [Back Panel] [Side Panel]

Virbac logo

EFFIPRO[®] TOPICAL SOLUTION FOR CATS

(Note to reviewer: font size of Cats will be 40% of the size of the largest letter in the brand name on the front panel)

Front Panel- Large, clear picture of a cat in the appropriate weight range for the product as packaged

FOR USE ONLY ON CATS AND [&] KITTENS 8 WEEKS OLD OR OLDER WEIGHING 1.5 LBS AND OVER

ACTIVE INGREDIENT

Fipronil.....9.59%

OTHER INGREDIENTS 90.41%

TOTAL..... 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

Front Panel- See Back Panel for First Aid and Additional Precautionary Statements
See Insert for Directions for Use

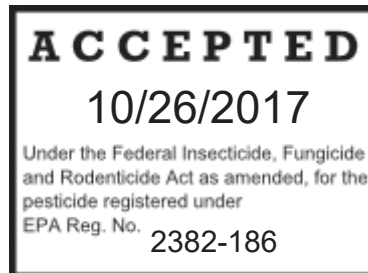
(OR)

See Back Panel for First Aid, Additional Precautionary Statements and Directions for Use

Front Panel

3 Applicators

[Net Contents:] 0.051 fl oz (1.5 mL), 3- 0.017 fl oz (0.5 mL) applicators



Back Panel and Insert

READ ENTIRE LABEL BEFORE EACH USE PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on cats ONLY. Do not use on cats or kittens less than 8 weeks of age, weighing less than 1.5 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Cats may experience some possible temporary irritation at the site of product application. If signs of sensitivity occur bathe your cat with mild soap or shampoo and rinse with large amounts of water. If signs continue, contact a veterinarian immediately. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats, or cats known to be sensitive to pesticide products. This product is not a substitute for prescribed heartworm preventative.

| FIRST AID | |
|---|--|
| IF SWALLOWED | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person. |
| IF IN EYES | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice. |
| IF ON SKIN OR CLOTHING | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice. |
| Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including human and veterinary health concerns, medical emergencies or pesticide incidents), you may call 1-800-338-3659, twenty-four (24) hours per day, seven (7) days per week. | |

(Note to reviewer: A box labeled "Side Effects" will be placed in the lower right hand corner of the back panel.)

Side Effects: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or contact Virbac at 1-800-338-3659.

Insert [Back Panel]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON CATS AND KITTENS ONLY.** For use ONLY on CATS and KITTENS 8 weeks old or older weighing at least 1.5 lbs. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

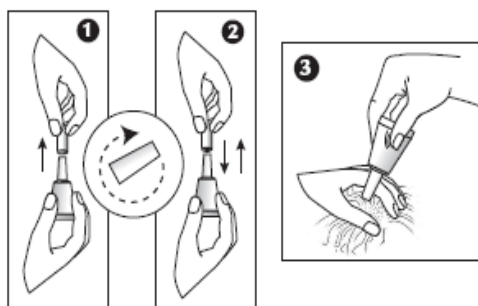
RESTRICTIONS

Do not use on cats or kittens less than 8 weeks of age weighing less than 1.5 lbs. Do not allow children to apply product. DO NOT USE ON DOGS, PUPPIES, OR RABBITS. DO NOT USE ON OTHER ANIMALS. Do not allow your cat to ingest this product. Do not apply more than one applicator to one cat per treatment regardless of the cat's weight. Do not apply more often than once a [per] month. In multiple cat households, do not allow cats to groom each other until the product has dried. Do not allow contact with treated area until completely dry. Your cat must be dry at the time of application and remain dry for 24 hours after application. To kill fleas, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit [carry] Lyme disease], [mosquitoes], and chewing lice; apply as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part cat's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on cat's skin.

Ensure that EFFIPRO® Topical Solution for Cats is not applied superficially on cat's hair.



Insert

FREQUENCY OF APPLICATION

[EFFIPRO® Topical Solution for Cats] [will kill] [Kills] fleas, ticks and chewing lice when applied monthly.

Fleas: [EFFIPRO® Topical Solution for Cats] [can control] [Controls] fleas [for] up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis [(FAD)], or if reinfestation is likely.

Ticks: [EFFIPRO® Topical Solution for Cats] [can kill] [Kills] ticks for a month or longer. Apply monthly where tick control is consistently needed.

[Mosquitoes: When applied monthly, EFFIPRO® Topical Solution for Cats can kill mosquitoes within 48 hours (for up to 28 days).]

Back Panel or Bottom Panel and Insert

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Back Panel] [Bottom Panel] [Insert]

[LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.]

Insert

[Detachable calendar monthly application reminder stickers with illustration of cat or kitten]

**Back Panel and Insert**

EPA Reg. No. 2382-186

EPA Est. No. [2382-FRA-1] [47420-DEU-1]

Virbac AH, Inc.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659
Made in France

[Questions or comments? Call: 1-800-338-3659]

Insert

© 2017 Virbac Corporation. All Rights Reserved. EFFIPRO® is a registered trademark of Virbac S.A.

Foil of Blister package

Virbac logo

EFFIPRO® Topical Solution for Cats

Only for use on cats & kittens ≥ 8 wks and [&] ≥ 1.5 lbs

0.017 fl oz [0.5 mL]

Contains fipronil (9.59%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-186

Applicator

Virbac logo

EFFIPRO® Topical Solution for Cats

Only for use on cats & kittens ≥ 8 wks and [&] ≥ 1.5 lbs

0.017 fl oz [0.5 mL]

Contains fipronil (9.59%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-186

EPA Est. No. [2382-FRA-1]

OPTIONAL MARKETING CLAIMS- ALTERNATE VARIATIONS APPEAR IN BRACKETS

The final label may include some or all of the optional text within each claim.

Multiple infestations

- [For] [convenient], [quick-acting], [long-lasting], [effective] control of [fleas], [ticks], [mosquitoes] [and] [chewing lice]
- [EFFIPRO® Topical Solution for Cats] contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, [mosquitoes] and chewing lice
- EFFIPRO® Topical Solution for Cats is also approved for control of flea, tick, [mosquito] and chewing lice infestations in breeding, pregnant and lactating queens.
- Persistent flea and tick efficacy for up to one month [4 weeks] [30 days]
- Prevents flea and tick [re]infestation for up to one month [4 weeks]
- Effective monthly application for fleas and ticks
- Effective monthly application against fleas and ticks
- Kills fleas and ticks for up to one month [4 weeks]
- Kills fleas, ticks, [mosquitoes] and [chewing] lice
- Apply monthly for control and prevention of fleas and ticks
- Protects against fleas and ticks for up to one month
- EFFIPRO® Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly

Fleas

- Fleas: [EFFIPRO® Topical Solution for Cats] [can control] [Controls] fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis [(FAD)], or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that transmit [bartonellosis], [tularemia] [and] [tapeworm]
- Kills fleas that may transmit diseases, including [bartonellosis], [tularemia] [and] [tapeworm] [infestations]
- Kill fleas that may cause Flea Allergy Dermatitis [(FAD)] or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of fleas that lasts [at least]1 month [4 weeks]

EPA Reg. No. 2382-186

October 6, 2017

Page 3 of 4

- Easy to apply, flea control that lasts [at least] 1 month [4 weeks]
- Protects your cat [and kitten 8 weeks of age or older weighing 1.5 lbs and over] from fleas for up to one month [4 weeks]
- Protects from fleas for up to one month [4 weeks]
- Kills adult fleas for up to one month [4 weeks]
- Monthly applications [(all year)] are recommended for control and prevention of fleas
- Regular [(monthly)] use breaks the flea life cycle
- EFFIPRO® Topical Solution for Cats [rapidly] kills fleas that may cause Flea Allergy Dermatitis [(FAD)]
- EFFIPRO® Topical Solution for Cats kills fleas
- Kills adult fleas which may cause Flea Allergy Dermatitis [(FAD)]
- Kills fleas that may cause flea-bite anemia
- Fleas do not have to bite to die
- Protects your cat from flea infestation that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [(FAD)]
- Protects cats [and kittens over 8 weeks old or older weighing 1.5 lbs and over] from fleas for at least one month [4 weeks]
- Prevents flea [re]infestation for at least one month [4 weeks]

Ticks

- Ticks: [EFFIPRO® Topical Solution for Cats] [can kill] [Kills] ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit [carry] Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis]
- Kills ticks including those that may transmit Lyme disease
- Kills ticks including Deer ticks [that may transmit Lyme disease], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills Brown dog ticks [*Rhipicephalus* spp], American dog ticks [*Dermacentor variabilis*], Deer ticks [*Ixodes* spp], and Lone Star ticks [*Amblyomma americanum*] for up to one month [4 weeks]
- Kills *Amblyomma americanum* [Lone Star ticks] for up to 4 weeks [one month]
- Protects [and kittens over 8 weeks old or older weighing 1.5 lbs and over] from ticks for up to one month

Mosquitoes

- Mosquitoes: When applied monthly, EFFIPRO® Topical Solution for Cats can kill mosquitoes within 48 hours (for up to 28 days).
- Kills mosquitoes
- Kills mosquitoes for up to 28 days

All others

- Chewing lice infestations are rapidly eliminated
- Can be used on breeding, pregnant and lactating queens
- Begins working upon application
- Once monthly application
- Single application lasts 4 weeks [one month]
- Easy and convenient application [applications]
- Easy to apply spot-on [topical] application
- Convenient, easy to apply
- Convenient to use [easy to apply]
- Convenient to use [easy to apply] topical application
- Convenient topical application [for cats]
- Easy, spot-on [topical] application
- Quick-drying, non-greasy
- Remains effective after exposure to sunlight
- Remains effective after bathing
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, or exposure to sunlight
- EFFIPRO® Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof [remains effective after bathing and swimming]
- Illustration of flea life cycle
- Illustration of flea
- Illustration of tick
- Picture or illustration of a cat or kitten in weight range of product as packaged